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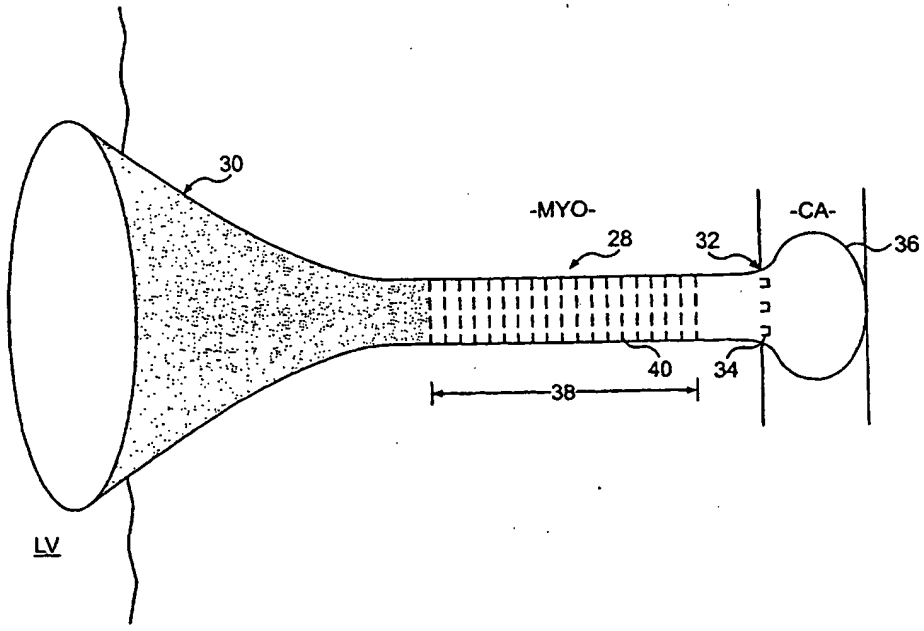

(57) Abstract: Described herein are methods and apparatus relating to a conduit placed in the heart wall between the left ventricle and the coronary artery. More particularly, the methods and apparatus accomplish one or more of the following goals, namely: (1) to accurately engage and align a conduit with the coronary artery; (2) to deliver a conduit into position in the heart wall; (3) to increase net forward flow through an opening or conduit from the left ventricle to the coronary artery; (4) to increase long term patency of a conduit between the left ventricle and coronary artery; (5) to accommodate wall thickness changes of the heart; and (6) to prevent

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METHODS AND APPARATUS FOR DIRECT CORONARY REVASCULARIZATION

Field of the Invention

The present invention relates to an apparatus for bypassing a blocked or stenosed blood vessel segment, and more particularly, to an apparatus and method for delivering a conduit or stent between the coronary artery and the left ventricle of the heart.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque which, at the very least, can reduce blood and oxygen flow to the heart muscle (myocardium), and may impair the efficiency of the heart's pumping action, and can lead to heart attack (myocardial infarction) and death. In some cases, these coronary arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

In a coronary bypass operation, one or more venous segments are inserted between the aorta and the coronary artery, or, alternatively, the distal end of an internal mammary artery is anastomosed to the coronary artery at a site distal to the stenosis or occlusion. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass graft (CABG) surgery, however, is a very intrusive procedure which is expensive, time-consuming, and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a heart-lung bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage or stenosis, or due to the risk of emboli.

Thus, there is a need for an improved coronary bypass system which is less traumatic to the patient.

Summary of the Invention

Briefly stated, the methods and apparatus described and illustrated herein generally relate to direct coronary revascularization, wherein a conduit or opening is provided from the left ventricle to the coronary artery, oftentimes the left anterior descending (LAD), to provide blood flow directly therethrough. These methods and apparatus are particularly useful when a blockage partially or completely obstructs the coronary artery, in which case the bypass conduit or opening is positioned distal to the blockage.

More particularly , the methods and apparatus described herein accomplish one or more of the following goals, namely: (1) to accurately engage and align a conduit with the coronary artery; (2) to deliver a conduit into position in the heart wall; (3) to increase net forward flow through an opening or conduit from the left ventricle to the coronary artery; (4) to increase long term patency of a conduit between the left ventricle and coronary artery; (5) to accommodate wall thickness changes of the heart; and (6) to prevent migration of the conduit.

Brief Description of the Drawings

FIGURE 1 is a schematic, cross-sectional view of a human heart, showing a conduit in the myocardium of the heart for forming a bypass shunt between the left ventricle and a coronary artery.

FIGURE 2 is a schematic view of a hinged conduit.

FIGURE 3 is a schematic view of another embodiment of a hinged conduit.

FIGURE 4A is a schematic side view of a bell shape stent having a web flange and an axially expandable region.

FIGURE 4B is a schematic side view of the distal end of the stent of **FIGURE 4A** showing more particularly the web flange in the coronary artery.

FIGURE 4C is a schematic side view of the stent and web flange of **FIGURE 4A**, showing a stylet holding the web flange closed.

FIGURE 5A is a schematic side view of an expandable device using a stylet down the center, and an outer catheter sleeve to keep the device compressed.

FIGURE 5B is a schematic side view of the device of **FIGURE 5A**, showing the device deployed.

FIGURE 6 is a schematic side view of a flange of a delivery tool to locate the, inner wall of the coronary artery.

FIGURE 7 is a schematic side view of a conduit having an expandable flange and external sleeve for delivering the device.

FIGURE 8 is a schematic side view of a device having an expansion chamber within the myocardium.

FIGURE 9 is a schematic side view of a device having an autologous valve made from an arterial flap.

FIGURE 10 is a schematic side view of a bypass opening between the left ventricle and the coronary artery, with the coronary artery cut and its proximal end inserted into the distal end over the bypass opening.

FIGURE 11 is a schematic side view of a bypass opening between the left ventricle and the coronary artery, with the coronary artery cut away from the heart and doubled back inside itself to create a valve with interior wall exposure only.

FIGURE 12 is a schematic side view of a bypass opening between the left ventricle and the coronary artery, showing a compliant restriction downstream in the artery.

FIGURE 13 is a schematic side view of a bypass opening between the left ventricle and the coronary artery, showing a device within the opening having a toroidal balloon therein.

FIGURES 14A-14B are schematic side views of a device having a fluidic valve between the left ventricle and the coronary artery.

FIGURE 15 is a schematic view of an active valve connected to the heart pacing function in the right atrium.

FIGURE 16 is a schematic side view of a bypass opening between the left ventricle and the coronary artery, showing a section of artery removed and inserted into the bypass opening.

FIGURES 16A-16B are schematic side view of the bypass opening of **FIGURE 16**, showing insertion of a spring embedded in the myocardium.

FIGURE 17 is a schematic side view of a device having a flattened diameter at the coronary artery end.

FIGURES 18-19 are schematic side views of a device having an inside surface made of a porous material through which heparin, or other non-clotting drug, can be infused.

FIGURE 20 is a schematic side view of a compliant tubing reinforced with rings or a spring.

FIGURE 21 is a schematic side view of a flexible conduit between the coronary artery and the left ventricle.

FIGURE 22 is a schematic side view a conduit having annular grooves.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the rest of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for comunicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Morevoer, the

conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined

with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods may be used. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (*e.g.*, the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (*e.g.*, the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

As illustrated in **FIGURE 1**, a coronary artery bypass is accomplished by disposing a left ventricular conduit 10 in a heart wall or myocardium MYO of a patient's heart PH. The conduit 10 preferably extends from the left ventricle LV of heart PH to a clogged coronary artery CA at a point downstream of a blockage BL. Conduit 10 is preferably made of a biocompatible material such as stainless steel or nitinol, although other materials such as Ti, Ti alloys, Ni alloys, Co alloys and biocompatible polymers may also be used. Conduit 10 may also be coated.

Engagement and Alignment with Artery

The embodiments described below relate to methods and apparatus for engaging and aligning a conduit between the left ventricle and coronary artery in a patient's heart.

FIGURE 2 illustrates a conduit 20 for connecting the left ventricle LV to the coronary artery CA. The conduit 20 comprises a solid tube that has a cut section 22 that can be bent over to align with the artery CA.

FIGURE 3 illustrates a conduit 24 similar to the conduit of **FIGURE 2,** which is more preferably a nitinol stent having a short hinged section 26 to align with the coronary artery.

In another embodiment, shown for instance in **FIGURE 19** described below, a conduit provided between the left ventricle and coronary artery further includes a flange, either rigid or flexible, that seats against the interior wall of the artery.

FIGURES 4A and **4B** illustrate a conduit 28 between the left ventricle and coronary artery which is preferably a nitinol stent. The proximal end 30 of the stent opening into the left ventricle preferably is heat set to have a bell shape to hold to the interior heart wall and to introduce flow. The distal end 32 preferably has small heat set fingers 34 which extend outward to anchor the stent against the interior wall of the coronary artery. A web flange 36 on the distal end 32 preferably comprises two or more rings which, when placed in the heart, open in the coronary artery to position the conduit while allowing blood flow. These rings are preferably shaped to extend outward in a curved configuration as shown in **FIGURE 4A** when deployed. Between the proximal and distal ends is an axially expandable region 38, provided by slots 40 cut in the region.

FIGURE 4C illustrates a stylet 42 used for inserting a conduit 28 having the web flange shown in **FIGURES 4A** and **4B**. More particularly, the stylet is inserted through the rings of the web flange to bring the rings together or closed for insertion. Removal of the stylet after the conduit is placed in the heart allows the rings to expand outward to the shape shown in **FIGURES 4A** and **4B.**

Delivery of Device

The embodiments described below relate to methods and apparatus for delivering a device between the left ventricle and the coronary artery.

In one embodiment, not shown, a coring knife is used to remove a plug or piece of the myocardium prior to insertion of a device or conduit therein.

FIGURES 5A-5B illustrate a conduit 44, which is preferably a nitinol device, using a stylet 46 down the center of the device. For a conduit such as shown in **FIGURE 4A,** an outer catheter sleeve 48 is used to keep the device compressed for insertion. A flange 50, or other protruding feature such as a step, on the stylet pushes the devices into

the heart wall, and a flange 52 on the sleeve controls the depth of insertion. **FIGURE 5B** illustrates the conduit 44 after it is inserted by removing the stylet and sleeve.

In another embodiment, not shown, a threaded device is provided for insertion into the myocardium as it is turned. The threaded device can be either the conduit itself between the left ventricle and coronary artery, or an insertion tool which holds the myocardium open for insertion of a nonthreaded conduit therethrough.

In another embodiment, not shown, a guidewire, catheter, conduit or other device is inserted from the left ventricle to the coronary artery. In order to accurately place one end of the device in or through the coronary artery, a radiopaque marker is placed on the end of the device to be inserted into the coronary artery. A second radiopaque marker is placed on the coronary artery, preferably on the outside of the heart over the coronary artery. In one embodiment, this second marker is preferably tubular in shape. Using fluoroscopy or other imaging technology, the catheter, guidewire or other device can be brought through the myocardium into an appropriate position inside or through the coronary artery by aligning the first marker with the second marker.

In another embodiment, shown in **FIGURE 6**, a delivery tool for inserting a conduit between the left ventricle and the coronary artery is provided. The tool 60 is preferably hollow to allow insertion of a conduit 62 therethrough. A flange 64 is provided on the tool 60 which is used to locate the inner wall of the artery when the tool is inserted. After the tool is inserted into the heart, the conduit can be inserted through the delivery tool into the myocardium. The flange on the delivery tool makes it easier to deliver the conduit to an appropriate location when there are differences in the exterior arterial wall thickness.

In another embodiment, shown in **FIGURE 7**, a conduit 66 is provided between the left ventricle and the coronary artery. On one end of the conduit, an expandable flange or cage 68 is provided, used to locate the artery. More particularly, the conduit 66 is delivered using an external sleeve 70 which is placed through the outer wall of the artery and held stationary. The conduit 66 is inserted through the sleeve, with the end opposite the end having the cage inserted first. The cage is collapsible within the sleeve. The conduit exits the sleeve into the coronary artery and through the myocardium.

Upon the release of the cage 68 from the sleeve, the cage expands to its expanded configuration to position itself in the artery and to maintain patency.

In another embodiment, not shown, a conduit having a flange or a bell shape, shown for example in **FIGURE 4A**, is held in a compressed configuration for delivery using sutures to hold the flange or bell shape in a small diameter until deployment. This prevents the need for an external sleeve through the myocardium. After the conduit is positioned, the sutures can be pulled off to deploy the device.

Increase Net Forward Flow

The embodiments described below relate to methods and apparatuses for increasing net forward flow in a conduit from the left ventricle to the coronary artery.

FIGURE 8 illustrates a device 102 to be placed in the myocardium between the left ventricle and coronary artery having an expansion chamber 104 within the myocardium. The chamber is designed to expand during systole, then flow during systole. One way valves 106, 108 are preferably provided at each end of the device to control flow.

FIGURE 9 illustrates the use of an arterial flap to form an autologous valve. An opening or conduit 112 is provided through the myocardium from the left ventricle to the coronary artery, downstream of blockage BL. A flap of arterial wall 110 is placed over the opening in the conduit facing the coronary artery to form the valve.

FIGURE 10 illustrates another embodiment using a cut portion of artery to form a valve over a bypass opening 112 between the left ventricle and coronary artery. The artery is cut at 114, and the portion 116 of the artery proximal to the cut is inserted into the portion 118 of the artery distal to the cut, over the bypass opening.

FIGURE 11 illustrates another embodiment when the artery is cut to form an autologous valve over a bypass opening, but wherein the portion of the artery forming the valve includes the inner wall of the artery. As shown, the artery is cut away from the heart, and doubled back inside to create a valve 110 over the bypass opening with interior wall exposure only.

In another embodiment, not shown, a conduit between the left ventricle and coronary artery has a conical or funnel shape, with one end larger than the other. This forms a passive valve.

In another embodiment, shown in **FIGURE 12**, a compliant restriction 120 is placed in the coronary artery downstream of a bypass opening 112 between the left ventricle and coronary artery. The site of the compliant restriction depends on the pressure of blood flow through the coronary artery CA. When flow pressure is low, for instance during diastole, the restriction blocks more flow to prevent backflow into the opening 112. During high pressure flow, *i.e.*, systole, the restriction does not impede flow and blood from the opening flows downstream past the compliant restriction.

In another embodiment, shown in **FIGURE 13**, a bypass opening or conduit 112 between the left ventricle and coronary artery is provided with a compressible material, more preferably a toroidal balloon 122. The balloon acts as a type of valve which increases the flow under systolic pressure. Under the high pressure flow of systole, the balloon compresses as shown in **FIGURE 13B** to increase blood flow. During low pressure diastolic flow, the balloon is decompressed to fill the opening and prevent blood flow. The balloon need not be the full length of the device. When the balloon is part of a conduit, the balloon preferably lines the inside of the conduit.

In another embodiment, shown in **FIGURE 14A**, a fluidic valve 124 is provided within a conduit 126 between the left ventricle and coronary artery. As shown in **FIGURE 14B**, the conduit 126 is divided, preferably into three regions. Reducing the effective inner diameter of the regions of the conduit decreases the low pressure (diastole) flow through each region due to the increased resistance.

In another embodiment, shown in **FIGURE 15**, a valve 128 for controlling blood flow through an opening or conduit 112 from the left ventricle to the coronary artery is provided. The valve is preferably an active valve connected to the heart pacing function of the right atrium.

In another embodiment, not shown, a ball valve is provided to control flow through an opening or conduit from the left ventricle to the coronary artery.

Long Term Patency

The embodiments described below relate to methods and apparatus for increasing long term patency of a conduit placed between the left ventricle and coronary artery.

In one embodiment,not shown, the conduit is an absorbable scaffold or stent seeded with the patient's epithelial cells.

In another embodiment, shown in **FIGURE 16,** a section of artery 130 proximal to a bypass opening or conduit 112 and distal to a blockage BL in the coronary artery is removed and inserted into the bypass opening. The section of artery 130 can either be lined with a bioabsorbable scaffold 132, or a permanent scaffold or stent can be placed on the outside of the section prior to inserting the section into the bypass hole or opening.

In another embodiment, not shown, when a metal conduit is used between the left ventricle and coronary artery, RF energy is used to kill growth on the conduit and to keep the conduit open.

In another embodiment, not shown, a conduit can be made open by burning a bypass hole with laser, electrosurgery or other ablation device, or by removing a core with a coring device. This hole can then be supported, as shown in **FIGURE 16A**, with a spring 160' embedded in the myocardium, which prevents the hole from closing during systolic contraction.

In another embodiment, shown in **FIGURE 17**, a conduit 134 is provided between the coronary artery and left ventricle having a proximal opening 132 to the left ventricle that is preferably round and a distal opening 138 to the coronary artery that is preferably a flattened bell. This flattened bell is formed by taking a larger diameter tube and flattening the distal end into a long oval.

In another embodiment, shown in **FIGURES 18** and **19,** a conduit 140 is provided between left ventricle and coronary artery having an inner surface 142 made of a porous material, preferably either metal or ceramic or a porous membrane. As shown in **FIGURE 18,** the wall of the conduit can be infused with heparin from a heparin reservoir 144 attached to a port 146 that may be located outside of the patient. This heparin is released through the porous surface 142 at a set rate. **FIGURE 19** illustrates another embodiment wherein a heparin reservoir 144 is provided within the conduit 140 itself surrounded by outer case 148. This reservoir 144 can also be infused with additional heparin from outside the body. Heparin is released through porous core 142. An ingrowth coating 150 is also provided on the outside of the conduit 140 to promote scar tissue growth to form a biornechanical bond to the surrounding myocardium, thereby preverlting movement of the conduit. For example, the coating may be a ceramic material to which the body has a tendency to bond. A similar porous layer for promoting

ingrowth is shown in **FIGURE 18** as outer layer 152. **FIGURE 19** also illustrates flange 154 for securing the conduit 140 to the coronary artery.

Accommodate Wall Thickness Changes

The embodiments described below relate to methods and apparatus for accommodating the wall thickness changes of the heart, for example, during systole and diastole.

As shown in FIGURE 20, a conduit 156 between the left ventricle and coronary artery is provided as a compliant, axially flexible tubing 158. Reinforcing rings 160 or a spring may be used to keep the tubing open. This is similar to a flexible duct, and allows the conduit to accommodate wall thickness changes while the rings keep the conduit open.

In another embodiment, shown and described above in **FIGURE 4A**, the conduit or stent is preferably cut to create axial expansion.

In another embodiment, shown in **FIGURE 21**, a flexible conduit 162 is provided between the left ventricle and coronary artery. The flexibility of the conduit accommodates the changes in wall thickness of the heart. The conduit is preferably sized to be larger toward the coronary artery CA than the left ventricle LV.

In another embodiment, not shown, the conduit between the left ventricle and coronary artery is preferably a woven sleeve, like a Chinese finger trap.

Prevent Migration

The embodiments described below relate to methods and apparatus for preventing migration of the conduit when placed between the left ventricle and coronary artery.

In one embodiment, not shown, the conduit is a mesh or stent type device. In another embodiment, annular or isolated barbs are provided on the conduit. In another embodiment, rigid or flexible flanges are provided on the conduit. In another embodiment, sutures are used to hold the conduit in place. In another embodiment, a porous outer layer is provided on the conduit to promote ingrowth with the surrounding heart muscle. In another embodiment, the conduit is provided with an hourglass, curved or fluted shape to prevent migration. **FIGURE 22** illustrates an embodiment where the conduit is provided with annular grooves. Grooves may also be provided longitudinally

along the conduit. In another embodiment, not shown, glue may be used to prevent migration of the conduit.

The embodiments illustrated and described above are provided merely as examples of certain preferred embodiments of the present invention. Various changes and modifications can be made from the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as described by the appended claims.

WHAT IS CLAIMED IS:

1. A conduit connecting a heart chamber to a coronary artery, comprising:

an elongate tubular body having a proximal end and a distal end and a lumen extending therethrough, the lumen at the proximal end opening into the heart chamber and the lumen at the distal end opening into the coronary artery; and

a flange at the distal end of the tubular body adapted to hold the conduit within the coronary artery.

2. The conduit of claim 1, wherein the flange is an expandable web flange.

3. The conduit of claim 1, wherein the proximal end of the conduit has a bell shape.

4. The conduit of claim 1, wherein the conduit has an axially expandable region between the proximal and distal ends.

5. The conduit of claim 1, wherein at least a portion of the conduit is held closed by sutures during delivery of the conduit to the heart chamber.

6. The conduit of claim 2, wherein the web flange is held closed by sutures during delivery of the conduit to the heart chamber.

7. A method for delivering a device to a desired location in a coronary vessel of a patient. comprising:

placing a first radiopaque marker at the desired location on the coronary vessel;

placing a second radiopaque marker on a portion of the device to be placed at the desired location; and

advancing the device through the patient toward the coronary vessel until the first and second markers are aligned with one another.

8. The method of claim 7, wherein the delivering includes delivering the device to a coronary artery.

9. The method of claim 7, wherein the device is a conduit.

10. The method of claim 9, wherein the desired location is on a wall of a coronary artery.

11. The method of claim 10, wherein the wall is adjacent to a heart wall.

12. The method of claim 10, wherein the portion of the conduit is an end of

the conduit.

13. The method of claim 7, wherein the desired location is on a wall of a coronary artery.

14. The method of claim 13, wherein the wall is adjacent a heart wall.

15. The method of claim 7, wherein the portion of the device is an end of the device.

16. The method of claim 7, wherein the device is chosen from a catheter and a guidewire.

17. The method of claim 7, wherein the device is a surgical delivery device.

18. A method of inserting a conduit into the heart wall between a heart chamber and a coronary vessel, comprising:

inserting a tool having a lumen extending therethrough into the heart wall through the coronary vessel, the tool having a mechanism thereon configured to control a depth of insertion of the tool through the heart wall; and

inserting the conduit through the lumen of the tool.

19. The method of claim 18, wherein the coronary vessel is a coronary artery.

20. The method of claim 19, wherein the mechanism is configured to engage with a wall of the coronary artery to stop the tool from being further inserted into the heart wall.

21. The method of claim 18, wherein the mechanism is a flange.

22. The method of claim 18, wherein the tool is a sleeve.

23. The method of claim 18, wherein the mechanism is a radiopaque marker.

24. A device for delivering a conduit in a heart wall, comprising:

a tool defining a lumen and having a distal end and a proximal end, said lumen being configured to receive the conduit for placement in the heart wall between a heart chamber and a coronary vessel; and

a depth insertion control mechanism on an external surface of the tool for controlling the depth of insertion of the tool within the heart wall.

25. The device of claim 24, wherein the coronary vessel is a coronary artery.

26. The device of claim 25, wherein the heart chamber is a left ventricle.

27. The device of claim 24, wherein the depth insertion control mechanism is a flange.

28. The device of claim 24, wherein the depth insertion control mechanism includes a radiopaque marker.

29. The device of claim 24, wherein the tool includes a sleeve.

30. The device of claim 25, wherein the tool is configured to be inserted through a wall of the coronary artery and into the heart wall.

31. The device of claim 30, wherein the depth insertion control mechanism is configured to indicate a stop insertion position of the tool when the depth insertion control mechanism reaches the wall of the coronary artery.

32. The device of claim 31, wherein the depth insertion control mechanism includes a flange configured to engage the wall of the coronary artery.

33. The device of claim 31, wherein the depth insertion control mechanism includes an radiopaque marker.

34. The device of claim 33, wherein a second radiopaque marker is provided on the wall of the coronary artery.

35. An apparatus for treating a heart, comprising:

a conduit configured to be placed in a heart wall, said conduit having an end configured to be positioned in flow communication with a coronary vessel; and

a stop mechanism on the end of the conduit, said stop mechanism configured to engage with a wall of the coronary vessel to hold the conduit in place with respect to the heart wall and coronary vessel.

36. The apparatus of claim 35, wherein the stop mechanism includes a flange.

37. The apparatus of claim 36, wherein the flange is expandable.

38. The apparatus of claim 37, wherein the flange has a web configuration.

39. The apparatus of claim 35, wherein the stop mechanism is configured as a cage.

40. The apparatus of claim 39, wherein the cage is expandable.

41. The apparatus of claim 35, wherein the stop mechanism is expandable.

42. The apparatus of claim 35, wherein the stop mechanism is configured to engage with a wall of the coronary vessel adjacent to the heart wall.

43. The apparatus of claim 35, wherein the coronary vessel is a coronary artery.

44. The apparatus of claim 35, wherein the conduit includes a stent.

45. The apparatus of claim 44, wherein the stent is expandable.

46. The apparatus of claim 35, wherein the stop mechanism includes heat set fingers.

47. The apparatus of claim 35, wherein the stop mechanism includes a bell shaped opening defined by the end of the conduit.

48. The apparatus of claim 47, wherein a second end of the conduit defines a round opening, said second end being opposite the end defining the bell-shaped opening.

49. The apparatus of claim 48, wherein the bell-shaped opening has a diameter larger than the round opening.

50. The apparatus of claim 47, wherein the bell-shaped opening is an elongated oval opening.

51. The apparatus of claim 35, further comprising a sleeve configured to deliver the conduit to the heart wall.

52. The apparatus of claim 51, wherein the sleeve is a catheter sleeve.

53. The apparatus of claim 35, wherein the conduit is held in a compressed configuration during delivery of the conduit to the heart wall.

54. The apparatus of claim 53, wherein the conduit is held in a compressed configuration with sutures.

55. The apparatus of claim 54, wherein the conduit has an expanded configuration when the sutures are removed.

56. A method for treating a heart, comprising:

providing a conduit having a stop mechanism on an end of the conduit;

placing the conduit in a heart wall such that the end of the conduit is positioned in flow communication with a coronary vessel; and

engaging the stop mechanism with a wall of the coronary vessel to hold the conduit in place with respect to the heart wall and coronary vessel.

57. The method of claim 56, wherein the engaging includes expanding the stop mechanism.

58. The method of claim 56, wherein the engaging includes engaging the stop mechanism with a wall of the coronary vessel adjacent to the heart wall.

59. The method of claim 56, wherein the coronary vessel is a coronary artery.

60. The method of claim 56, wherein the conduit is a stent.

61. The method of claim 60, wherein the placing includes expanding the stent.

62. The method of claim 56, further comprising delivering the conduit to the heart wall via a sleeve.

63. The method of claim 62, wherein the sleeve is a catheter sleeve.

64. The method of claim 56, further comprising delivering the conduit to the heart wall in a compressed configuration.

65. The method 64, wherein the conduit is held in the compressed configuration with sutures.

66. The method of claim 65, wherein the placing includes removing the sutures to expand the conduit.

67. An apparatus for treating a heart, comprising:

a conduit configured to be placed in a heart wall, said conduit having an end defining a flattened oval-shaped opening configured to be in flow communication with a coronary vessel when the conduit is placed in a heart wall.

68. The apparatus of claim 67, wherein the conduit has a second end defining a second opening configured to be in flow communication with a heart chamber surrounded by the heart wall.

69. The apparatus of claim 67, wherein the coronary vessel is a coronary artery.

70. The apparatus of claim 67, wherein the heart wall surrounds a left ventricle.

71. The apparatus of claim 68, wherein the second opening is round.

72. The apparatus of claim 67, wherein the oval-shaped opening is bell-shaped.

73. The apparatus of claim 67, wherein the conduit is configured to be held in a compressed configuration during delivery to the heart wall.

74. The apparatus of claim 73, wherein the conduit is configured to be held in the compressed configuration via a sleeve.

75. The apparatus of claim 73, wherein the conduit is configured to be held in the compressed configuration via sutures.

76. The apparatus of claim 67, wherein the conduit is expandable.

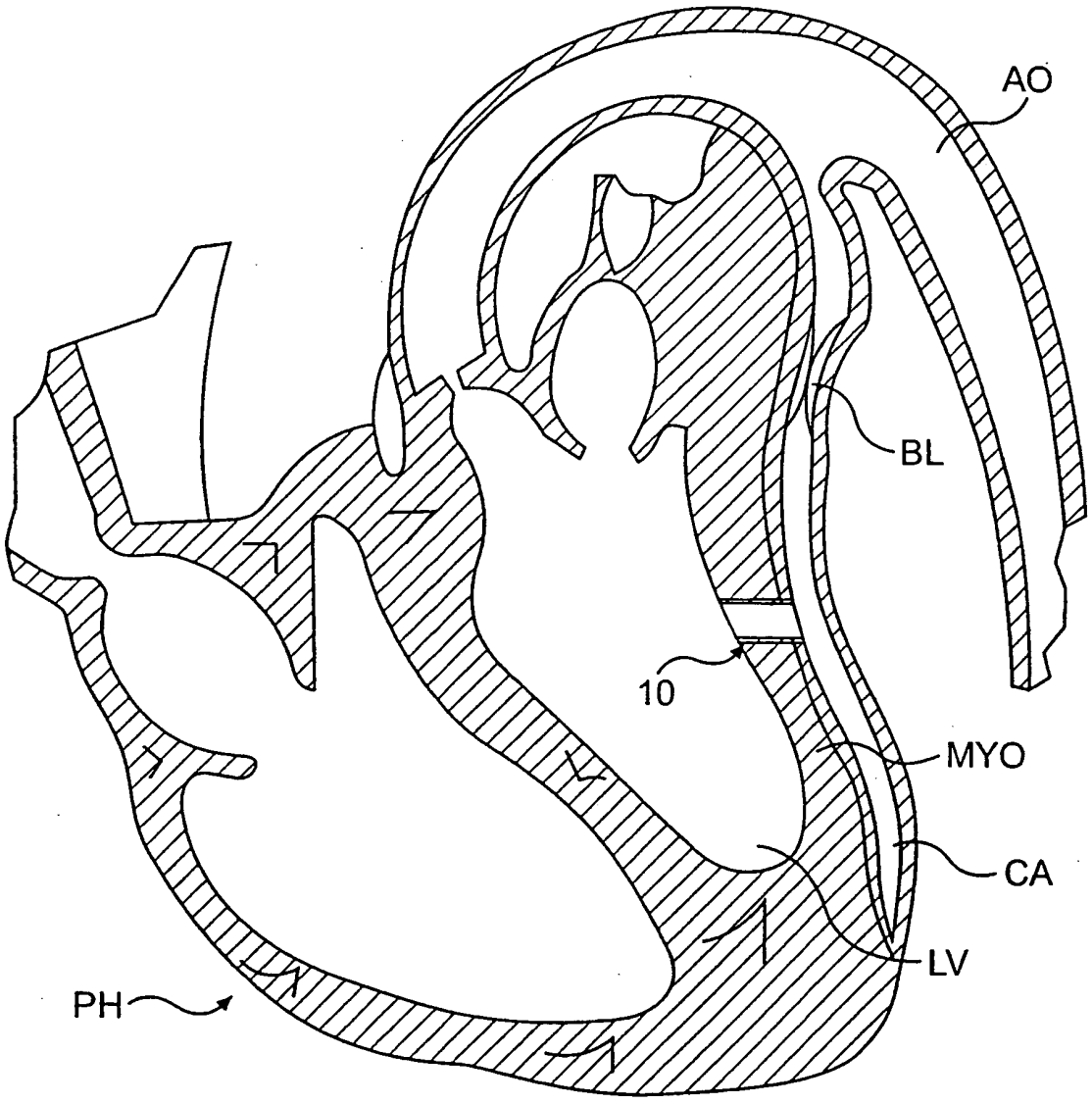

FIG. 1

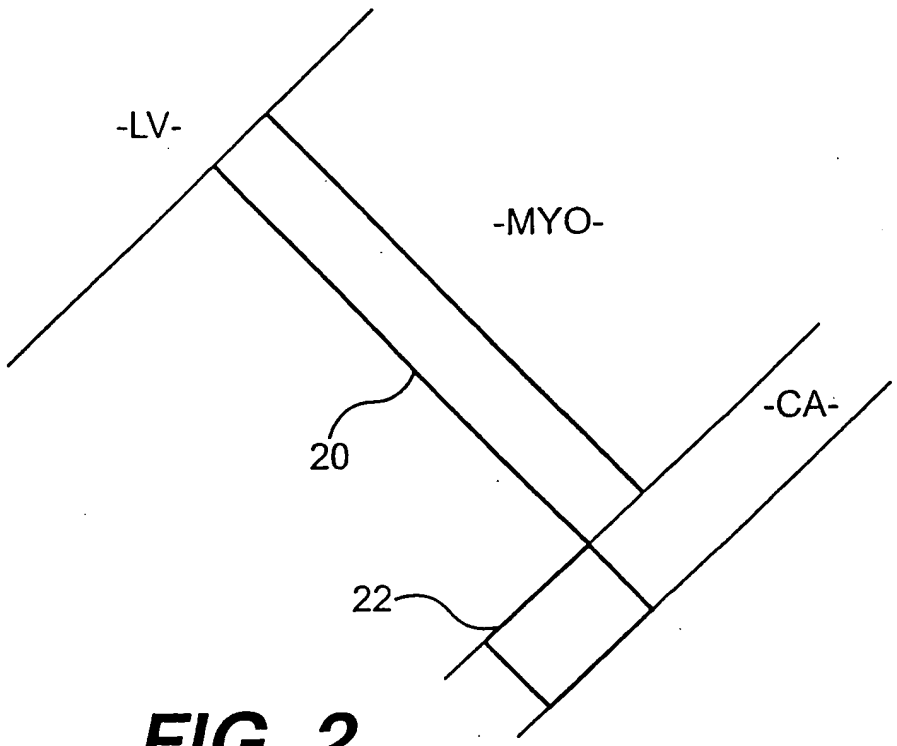

FIG. 2

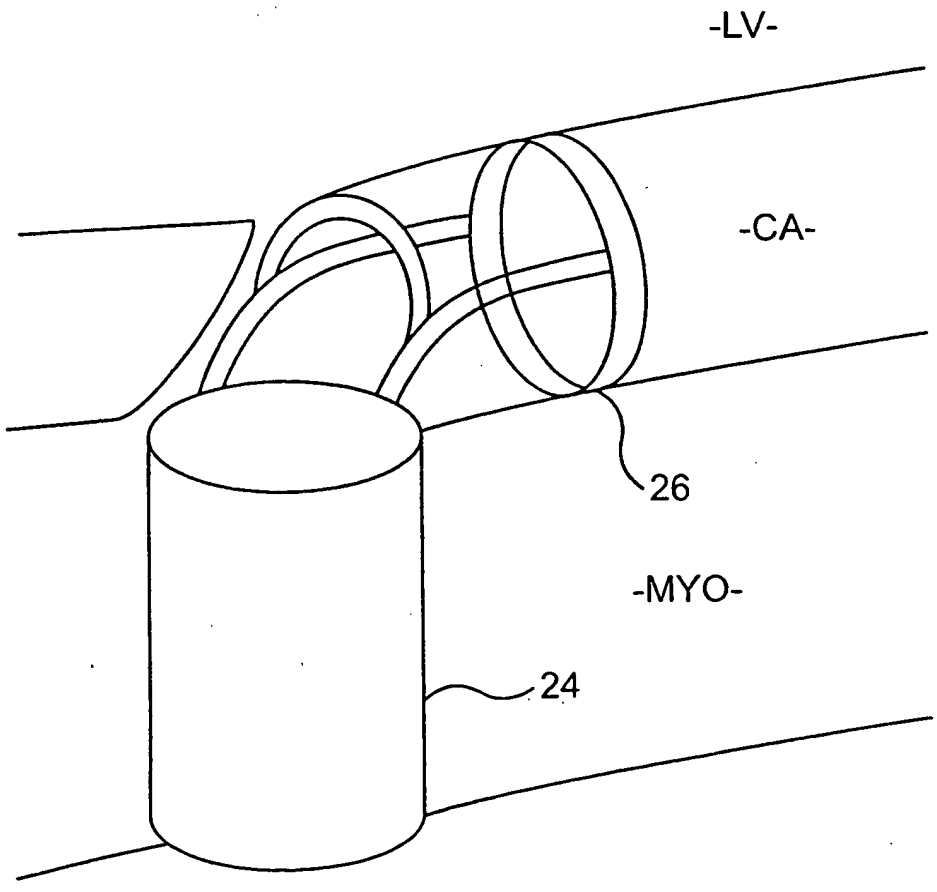

FIG. 3

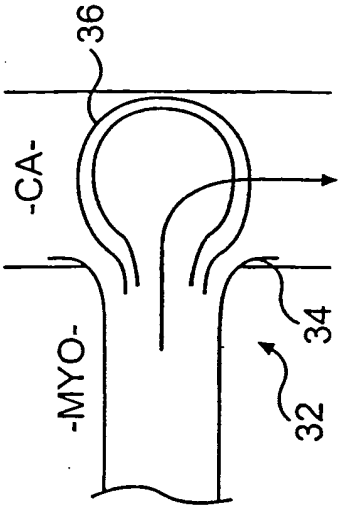

FIG. 4B

FIG. 4A

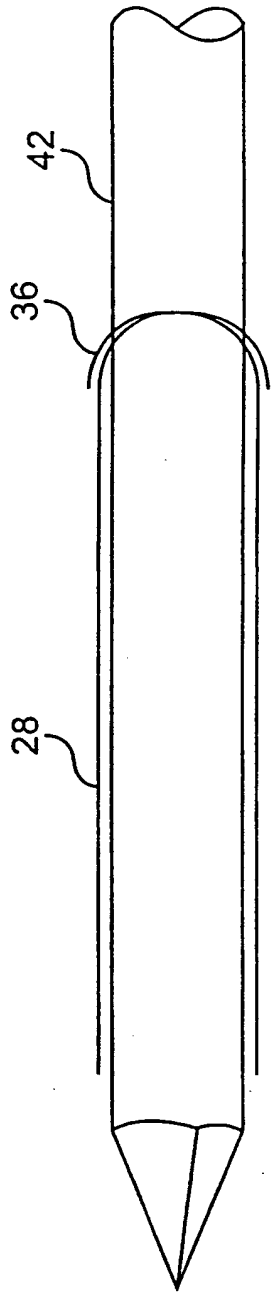

FIG. 4C

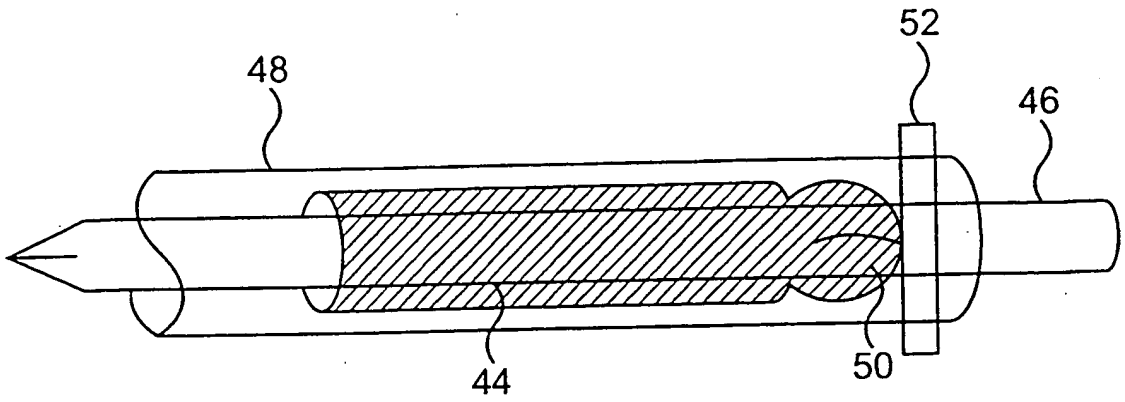

FIG. 5A

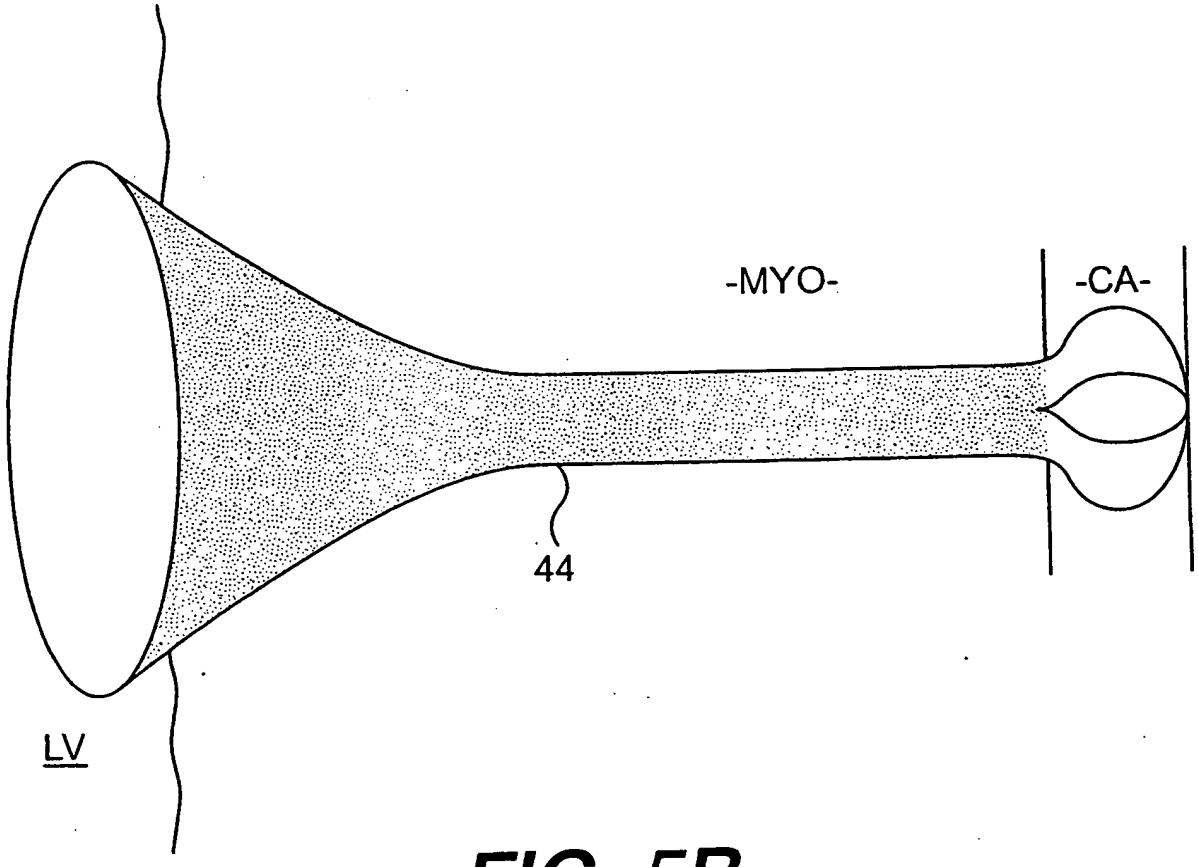

FIG. 5B

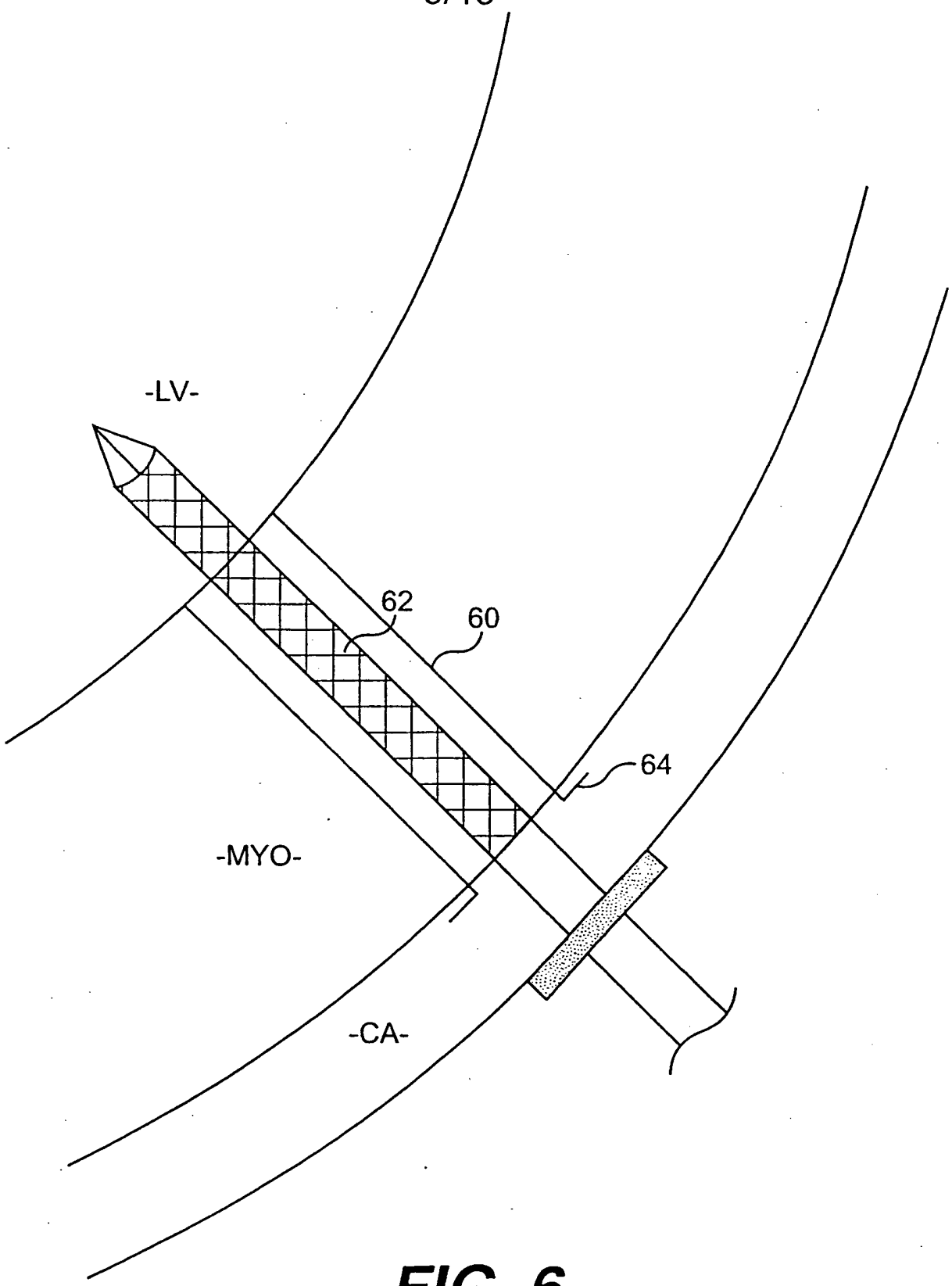

FIG. 6

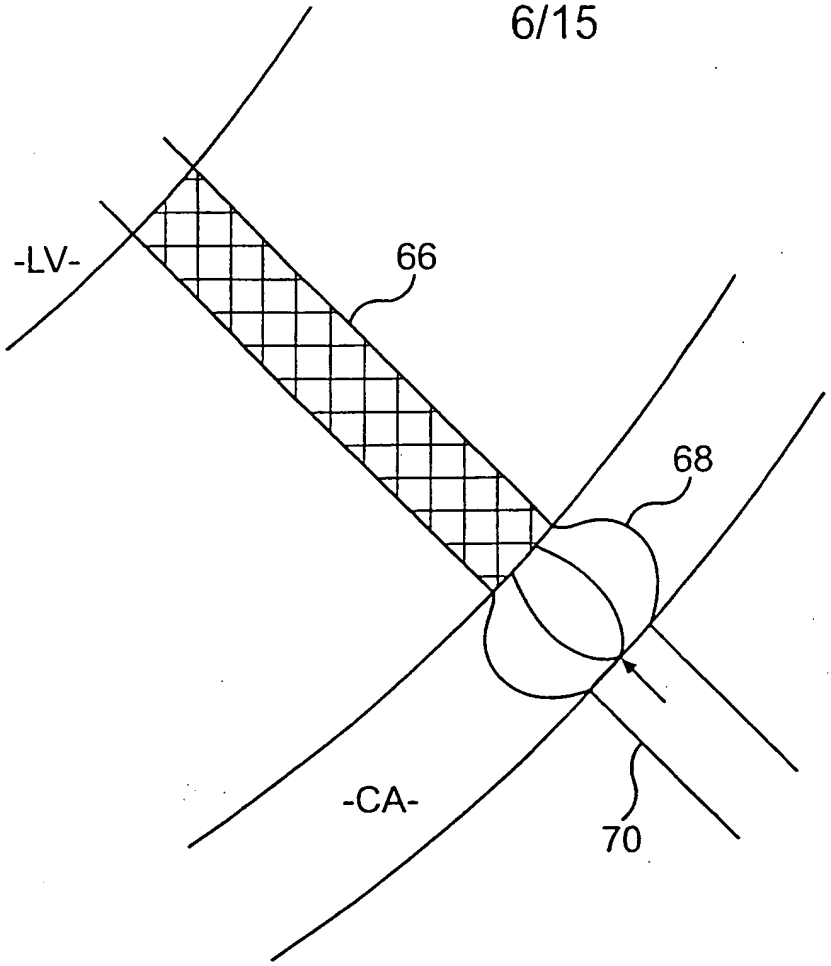

FIG. 7

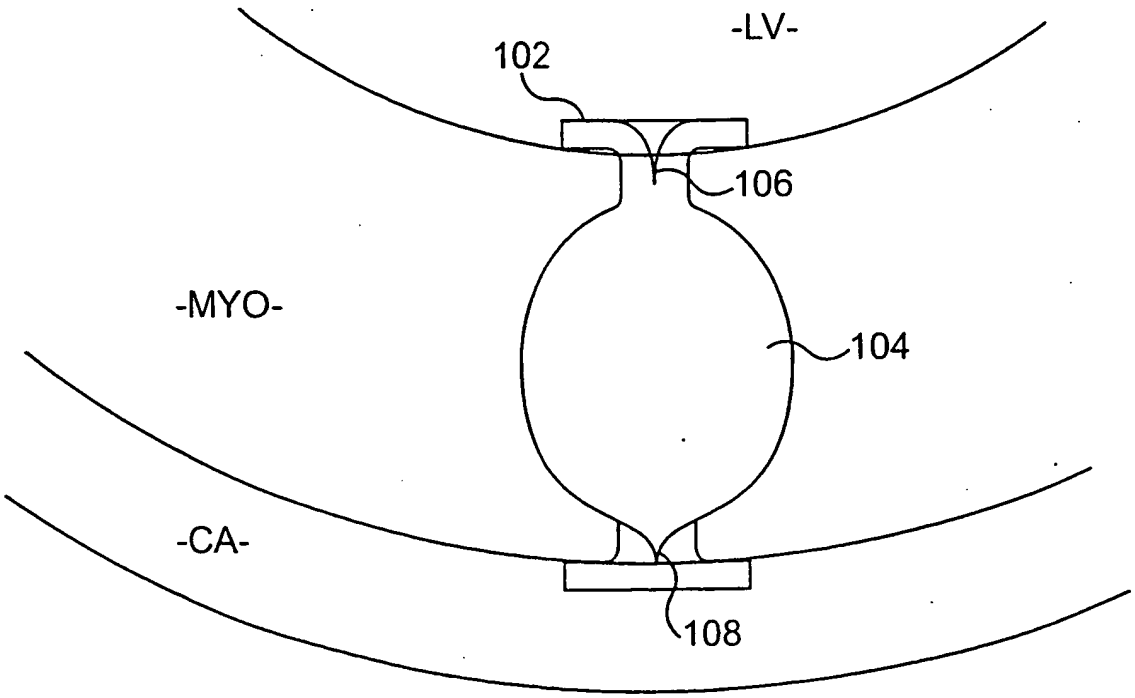

FIG. 8

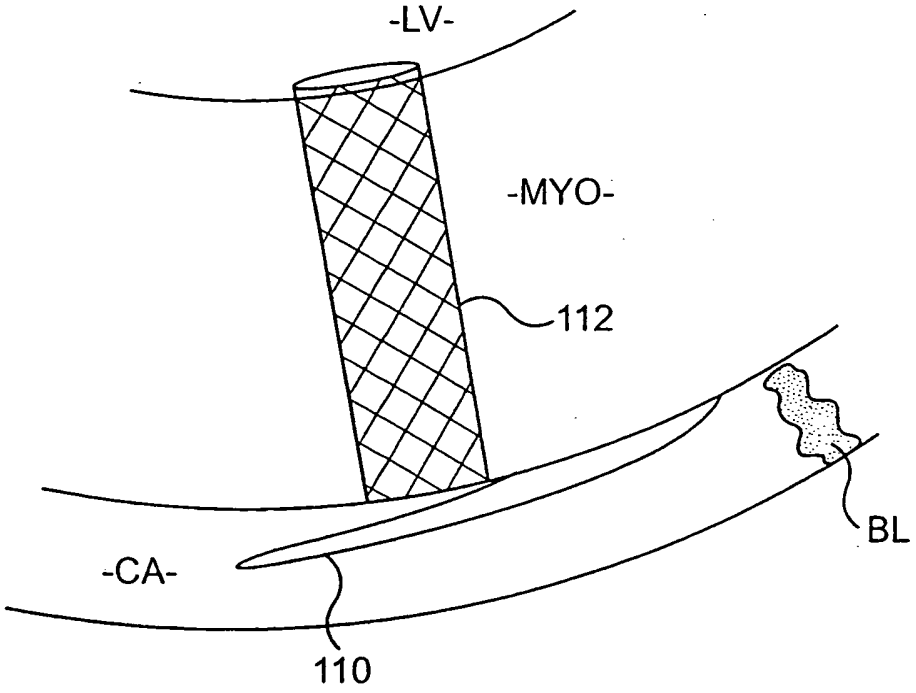

FIG. 9

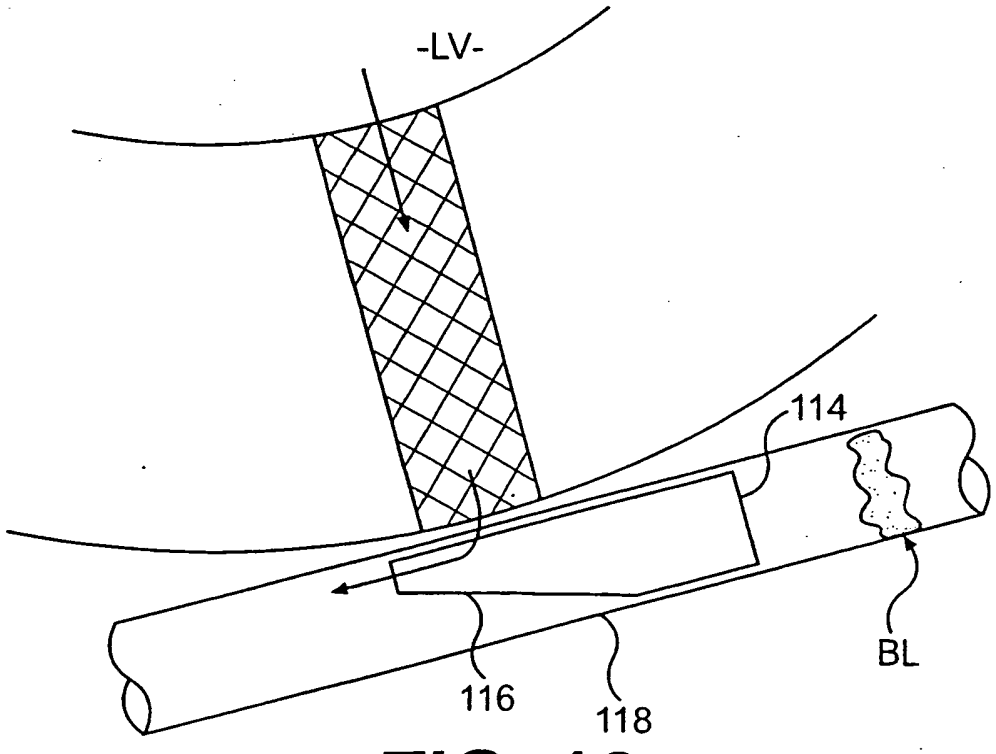

FIG. 10

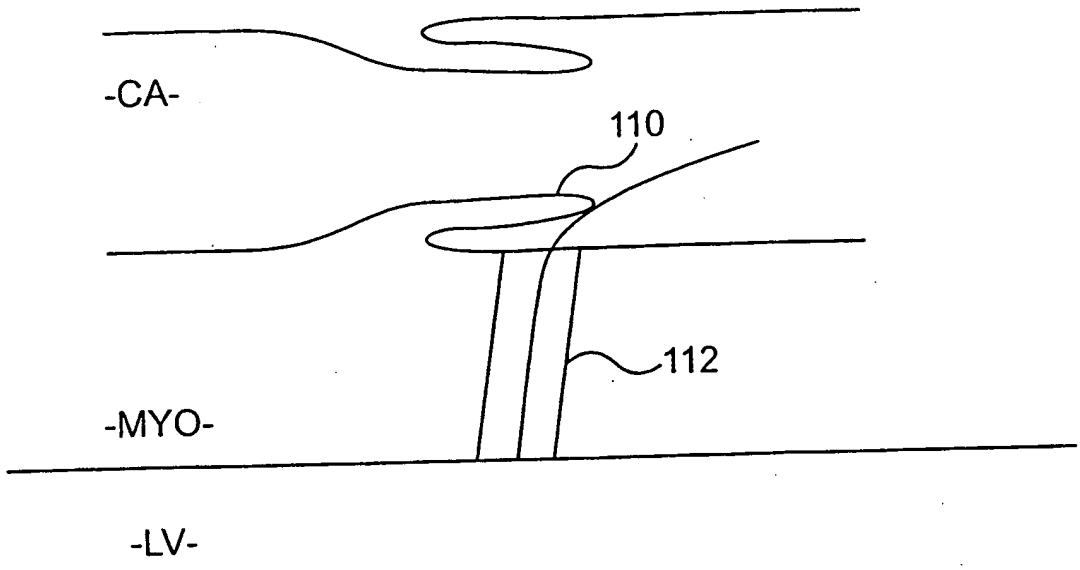

FIG. 11

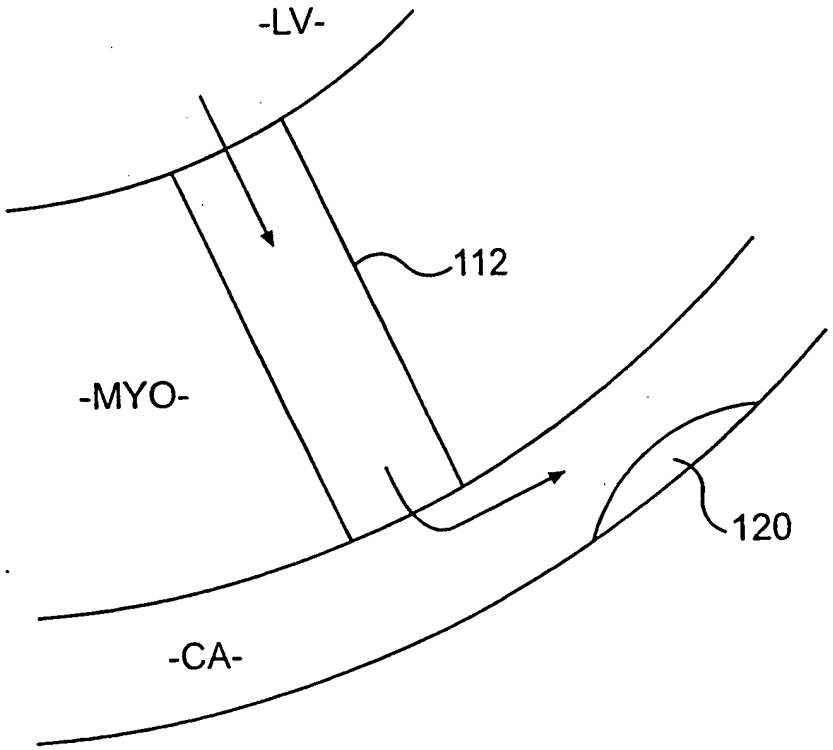

FIG. 12

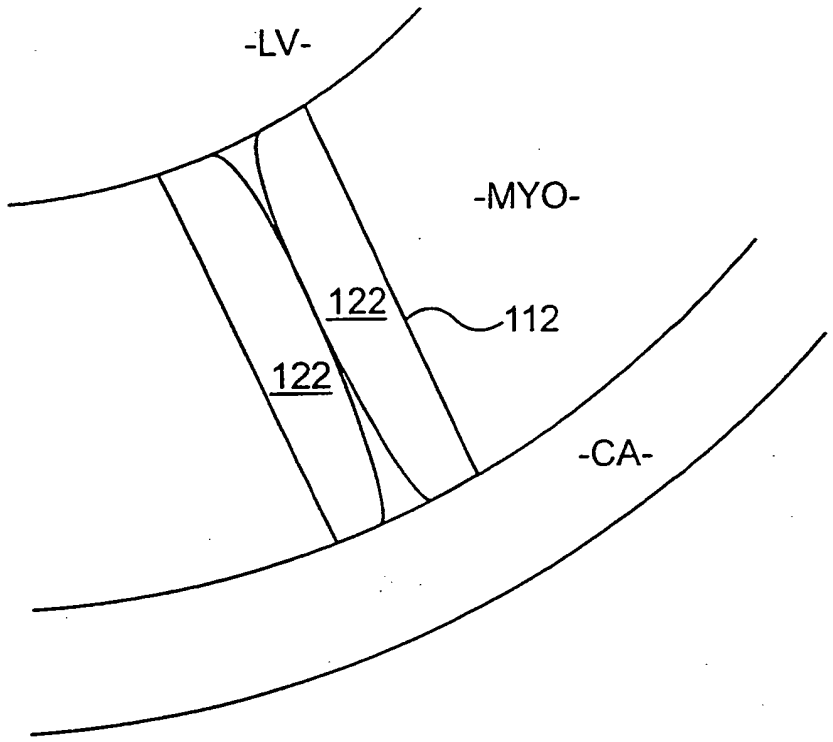

FIG. 13A

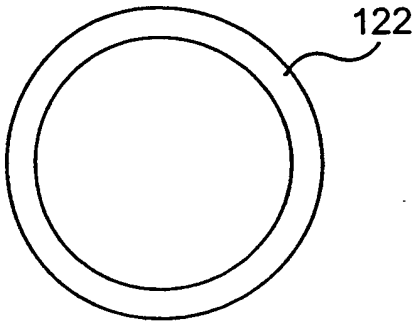

FIG. 13B

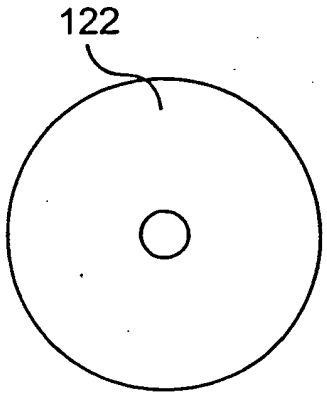

FIG. 13C

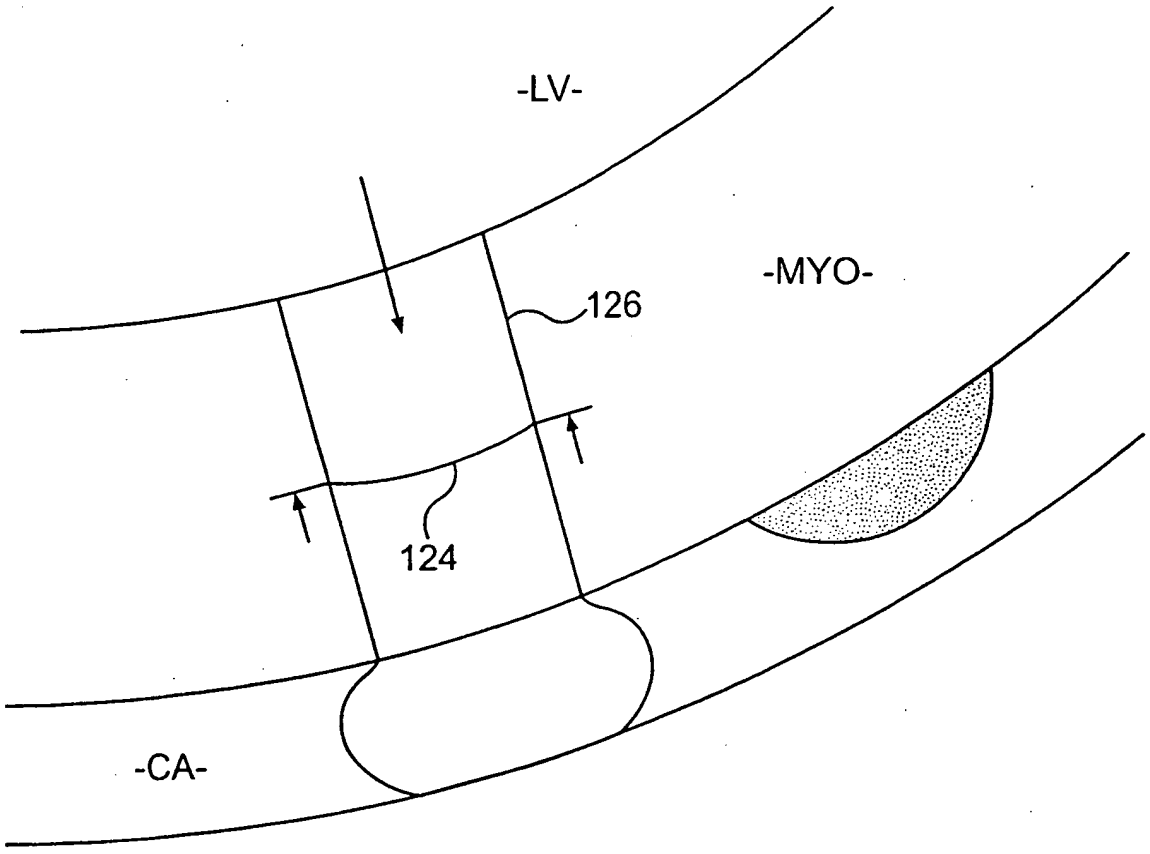

FIG. 14A

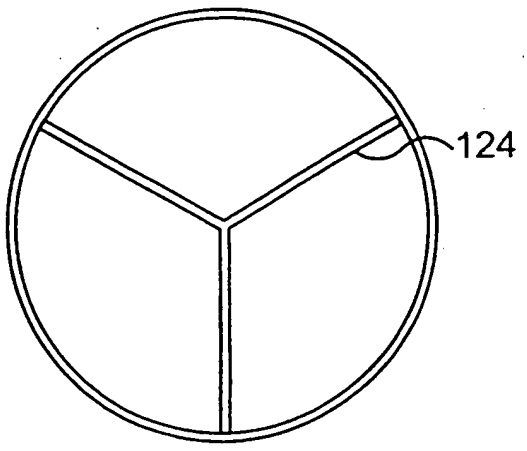

FIG. 14B

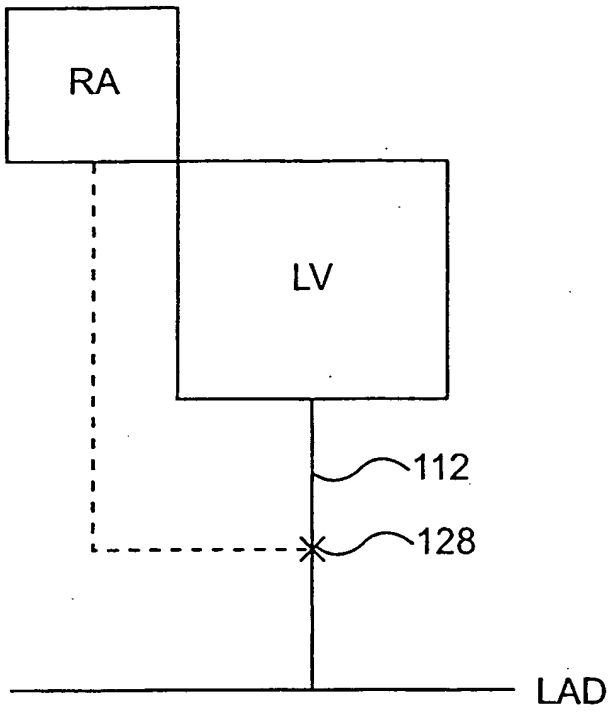

FIG. 15

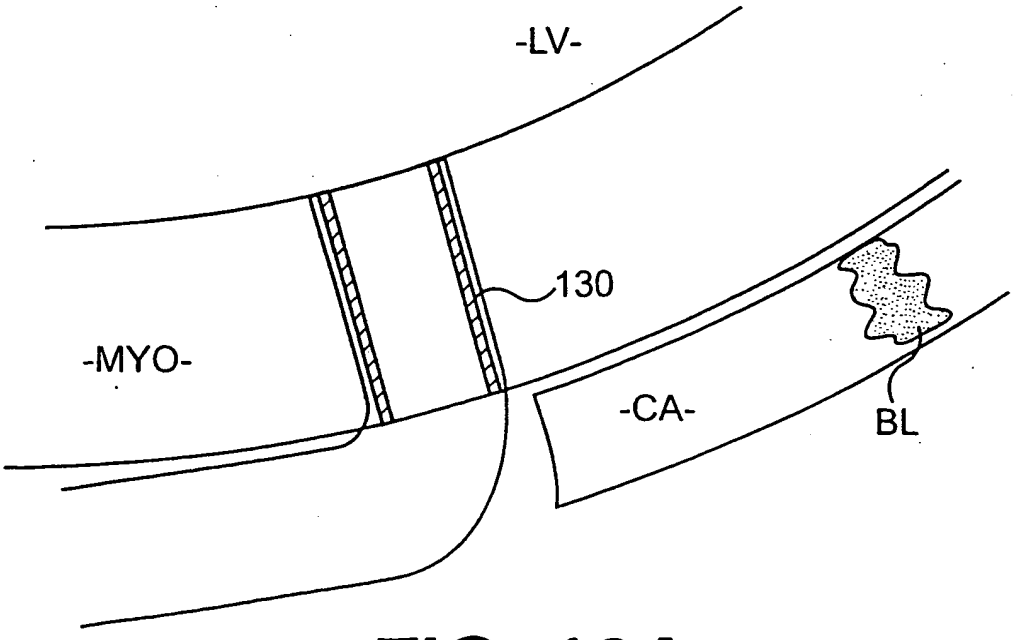

FIG. 16A

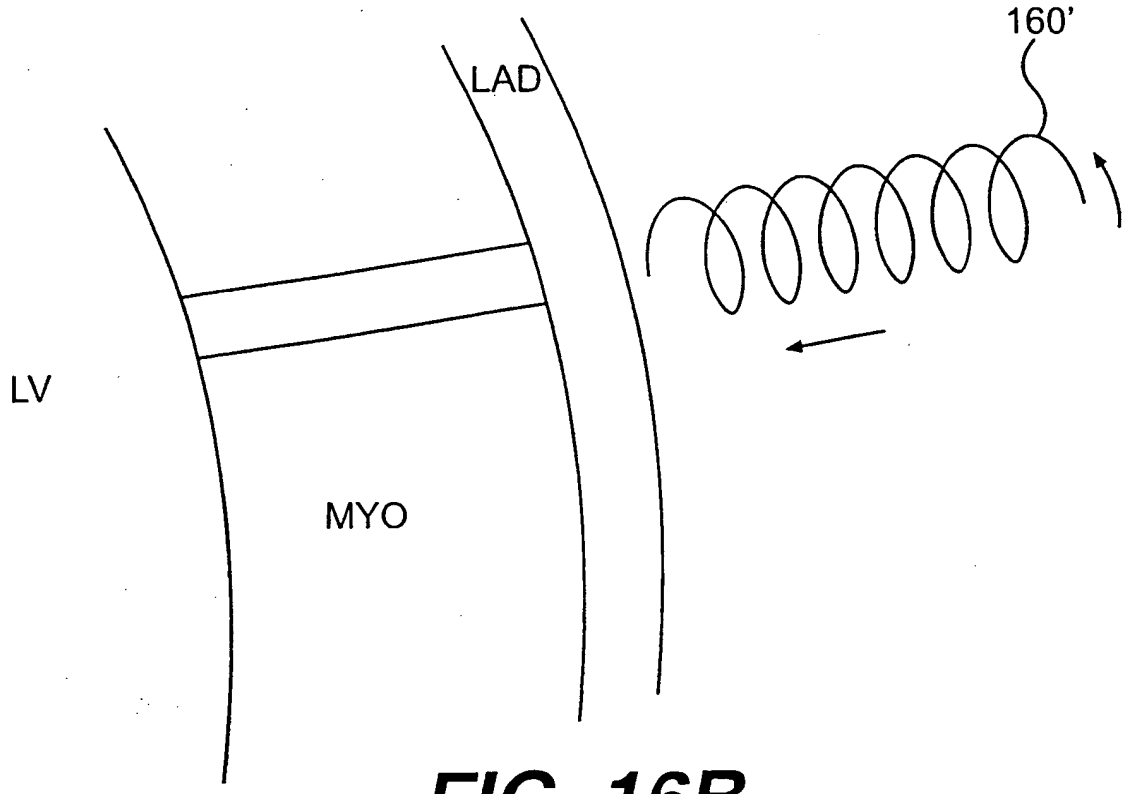

FIG. 16B

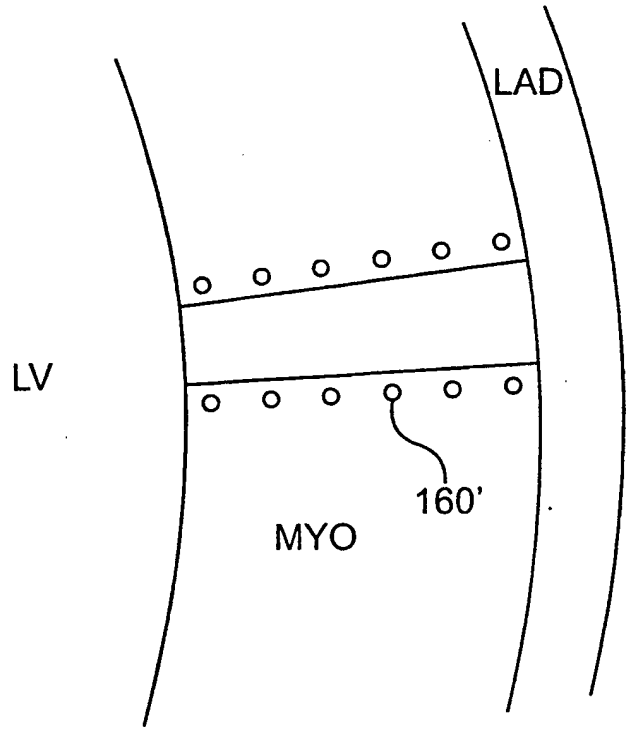

FIG. 16C

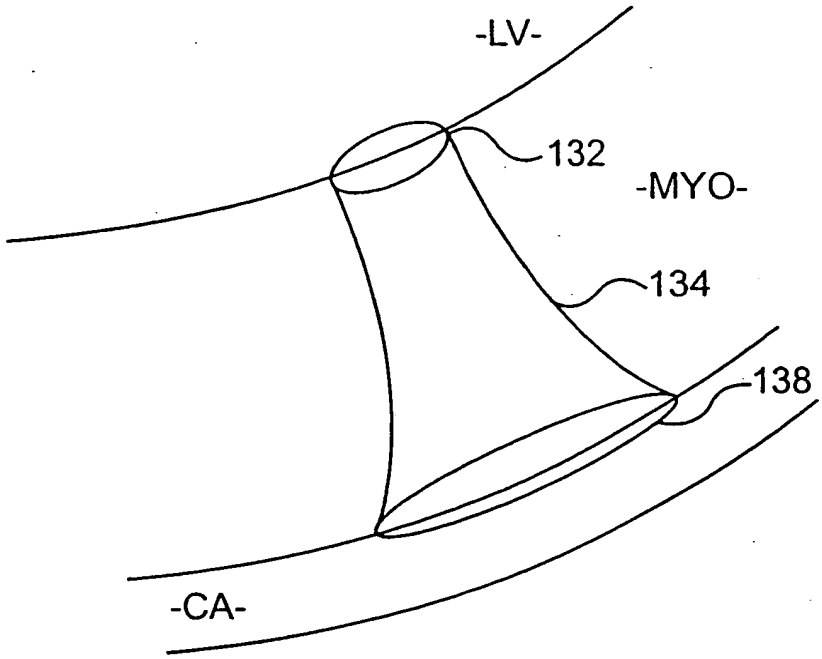

FIG. 17

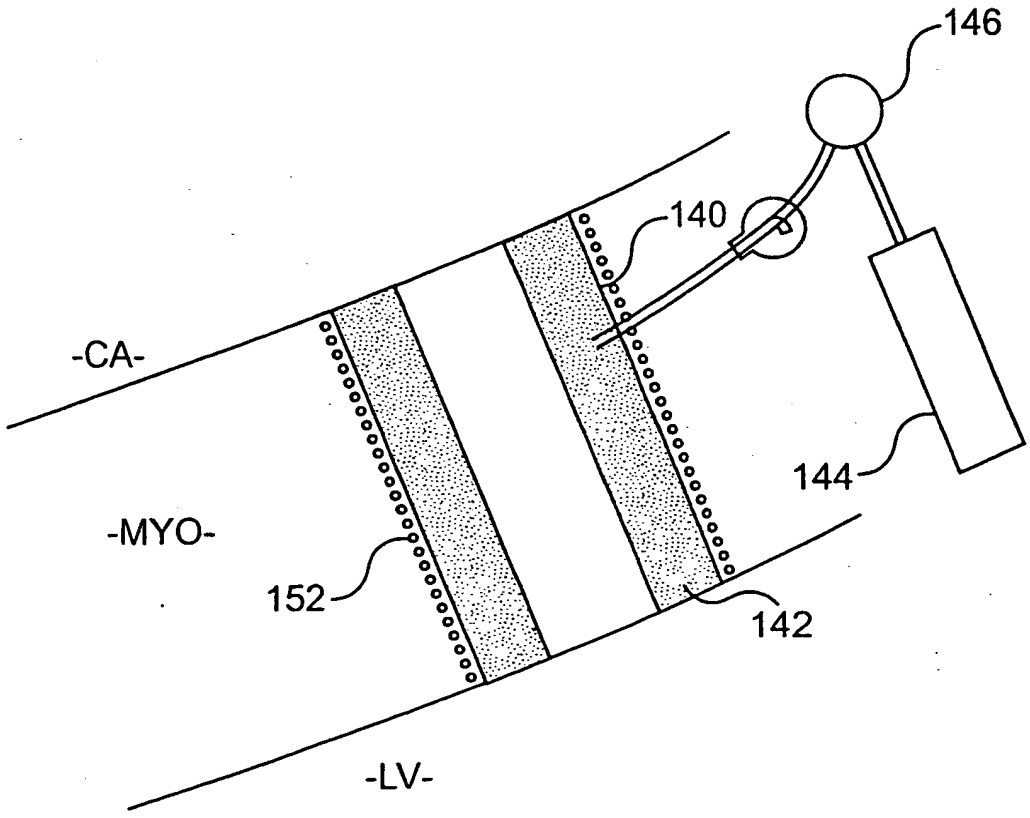

FIG. 18

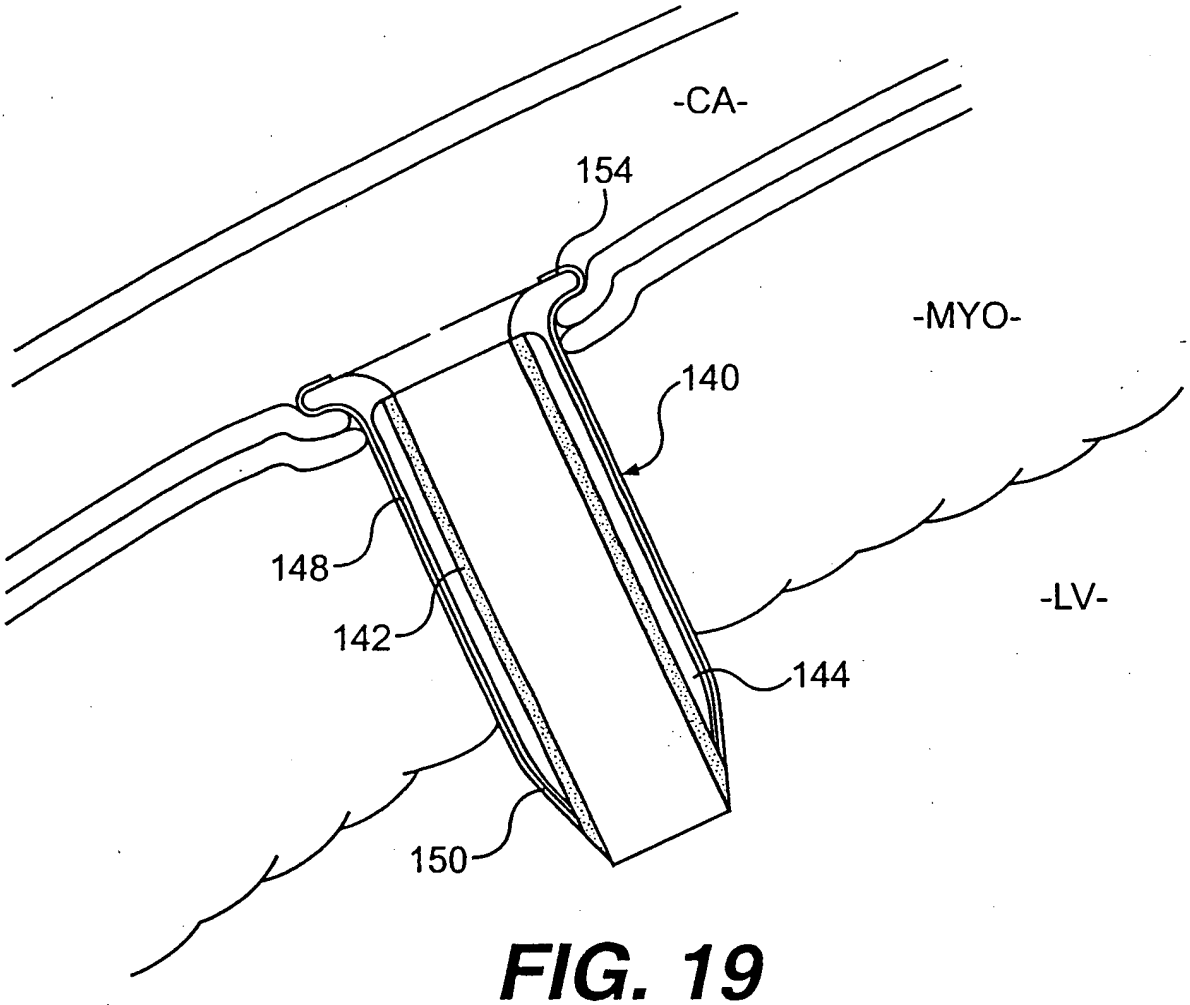

FIG. 19

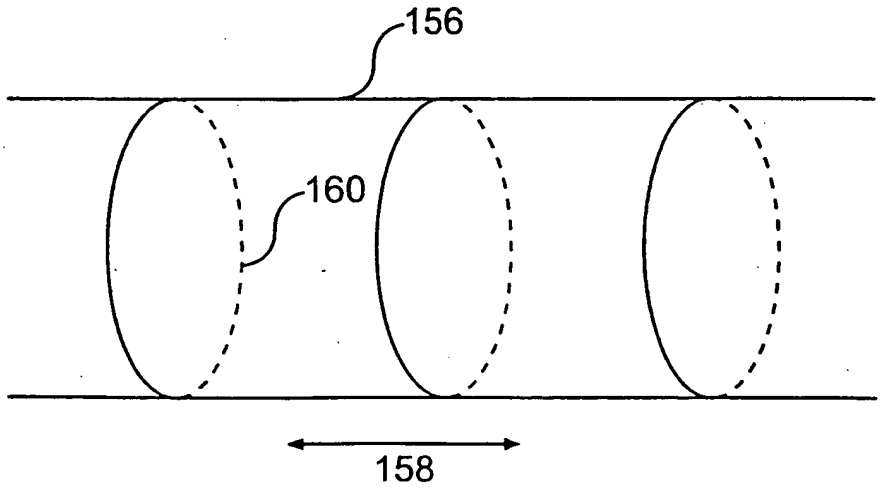

FIG. 20

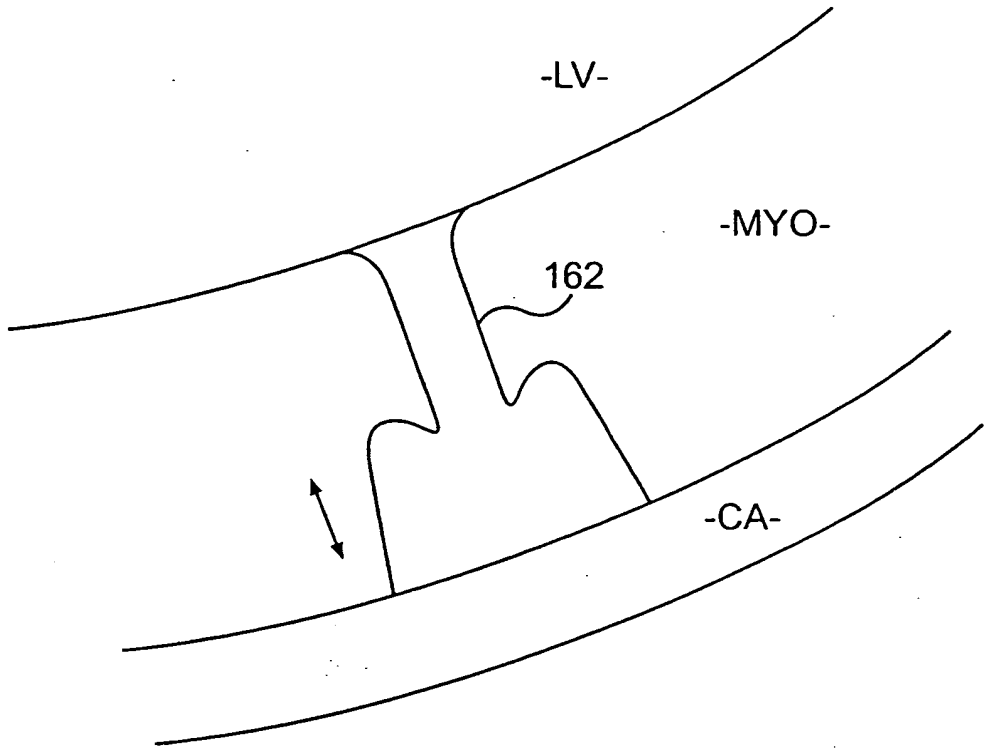

FIG. 21

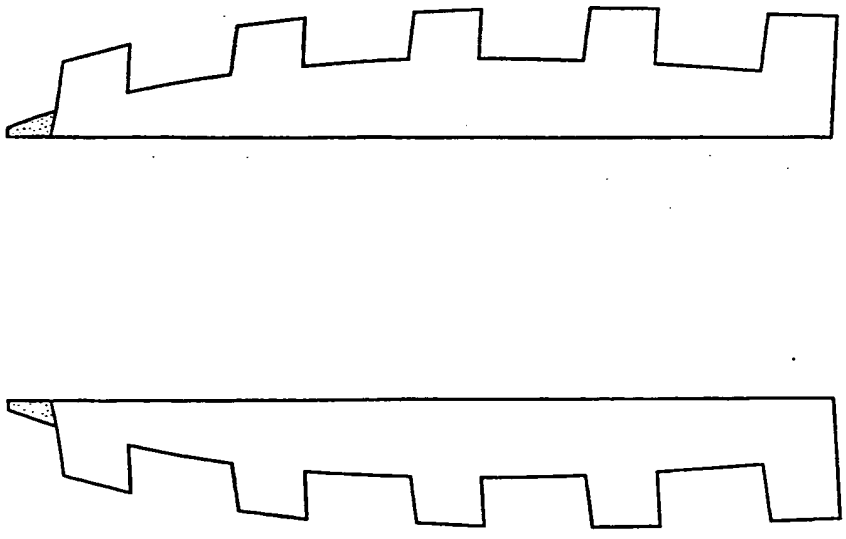

FIG. 22

INTERNATIONAL SEARCH REPORT

Interna] Application No
PCT/US 00/20973

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 824 071 A (SHMULEWITZ ASCHER ET AL) 20 October 1998 (1998-10-20) figures 5,7,10,11A column 6, line 30 - line 47 column 6, line 57 -column 7, line 32 column 7, line 66 -column 8, line 13 column 8, line 63 -column 9, line 26 column 10, line 53 - line 67	24-36, 42,43, 51-53
A	---	1,67-76
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 November 2000	15/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,	

INTERNATIONAL SEARCH REPORT

Intern: al Application No
PCT/US 00/20973

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 6 080 163 A (HUSSEIN HANY ET AL) 27 June 2000 (2000-06-27) figures 2,6,7 column 3, line 33 - line 65 column 4, line 34 - line 42	1,24-29, 35,36, 42-44, 51-53
A	---	67-74
P,X	WO 99 40868 A (VENTRICA INC) 19 August 1999 (1999-08-19) figures 20-34 page 11, line 12 - line 32 page 16, line 1 - line 10 page 29, line 20 -page 30, line 31 page 31, line 6 -page 32, line 17	1,35,36, 42-44, 67-71, 73,74
A	-----	2-6,24, 37-41, 45-55, 72,75,76

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna[illegible]l Application No
PCT/US 00/20973

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